

Atty. Dkt. No. 074129-0492

Appl. No. 10/019,786

RECEIVED  
CENTRAL FAX CENTER

SEP 20 2006

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) A sustained release composition comprising  
a pharmacologically active substance or its salt,  
a hydroxynaphthoic acid or its salt and  
~~a lactic acid-glycolic acid polymer or its salt;~~ a polymer chosen from lactic acid homopolymers and salts thereof and lactic acid-glycolic acid polymers and salts thereof,  
wherein the ~~a~~ product of the weight average molecular weight of said ~~lactic acid-glycolic acid~~  
~~polymer and by the amount (μmol) in μmol~~ of the terminal carboxyl group per unit mass (g)  
~~in grams~~ of said ~~lactic acid-glycolic acid~~ polymer is ranges from 1,200,000 to 3,000,000  
(inclusive).
2. (Original) The sustained release composition according to claim 1, wherein the  
pharmacologically active substance is a physiologically active peptide.
3. (Original) The sustained release composition according to claim 1, wherein the  
pharmacologically active substance is an LH-RH derivative.
- 4-5. (Canceled).
6. (Currently amended) The sustained release composition according to claim 1, wherein  
the % molar ratio in said polymer between lactic acid and glycolic acid is ranges from 100/0  
to 40/60.
7. (Currently amended) The sustained release composition according to claim 1, wherein  
the % molar ratio in said polymer between lactic acid and glycolic acid is 100/0.
8. (Currently amended) The sustained release composition according to claim 1, wherein  
the weight average molecular weight of the polymer is ranges from about 3,000 to about  
100,000.

Atty. Dkt. No. 074129-0492  
 Appl. No. 10/019,786

9. (Currently amended) The sustained release composition according to claim 8, wherein the weight average molecular weight is ranges from about 20,000 to about 50,000.
10. (Original) The sustained release composition according to claim 3, wherein the LH-RH derivative is a peptide represented by Formula: 5-oxo-Pro-His-Trp-Ser-Tyr-Y-Leu-Arg-Pro-Z wherein Y denotes DLeu, DAla, DTrp, DScr(tBu), D2Nal or DHis(ImBzl), and Z denotes NH-C<sub>2</sub>H<sub>5</sub> or Gly-NH<sub>2</sub>.
11. (Currently amended) The sustained release composition according to claim 1, wherein the amount (~~μmol~~) in μmol of the terminal carboxyl group of the polymer is ranges from 50 to 90 μmol per unit mass (~~g~~) in grams of the polymer.
12. (Currently amended) The sustained release composition according to claim 3, wherein the molar ratio between the hydroxynaphthoic acid or its salt and the LH-RH derivative or its salt is ranges from 3:4 to 4:3.
13. (Original) The sustained release composition according to claim 3 which contains the LH-RH derivative or its salt in an amount of 12 % by weight to 24 % by weight based on the sustained release composition.
14. (Original) The sustained release composition according to claim 1, wherein the physiologically active substance or its salt is a slightly water-soluble or water-soluble substance.
15. (Original) The sustained release composition according to claim 1 which is a formulation for injection.
16. (Currently amended) The A method for producing a sustained release composition according to claim 1 which comprises removing a solvent from a mixture of
  - a pharmacologically active substance or its salt,
  - ~~a lactic acid-glycolic acid polymer or its salt,~~ a polymer chosen from lactic acid homopolymers and salts thereof and lactic acid-glycolic acid polymers and salts thereof, and
  - a hydroxynaphthoic acid or its salt.

Atty. Dkt. No. 074129-0492  
Appl. No. 10/019,786

17. (Currently amended) The method according to claim 16 which comprises mixing the pharmacologically active substance or its salt with a solution of the ~~lactic acid-glycolic acid~~ polymer or its salt and the hydroxynaphthoic acid or its salt in an organic solvent, dispersing the mixture, and then removing the organic solvent.
18. (Original) The method according to claim 16, wherein the pharmacologically active substance or its salt is an aqueous solution containing the pharmacologically active substance or its salt.
19. (Original) The method according to claim 16, wherein the salt of the pharmacologically active substance is a salt with a free base or acid.
20. (Original) A medicament comprising a sustained release composition according to claim 1.
21. (Currently amended) A prophylactic or therapeutic agent against prostate cancer, prostate hyperplasia, endometriosis, hysteromyoma, metrofibroma, precocious puberty, dysmenorrhea or mammary cancer or an a contraceptive containing a sustained release composition according to claim 3.
22. (Original) The sustained release composition according to claim 1, wherein the pharmacologically active substance or its salt is released over a period of at least 6 months or longer.
23. (Original) A sustained release composition comprising a pharmacologically active substance or its salt, 1-hydroxy-2-naphthoic acid or its salt and a biodegradable polymer or its salt.